

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION)	
)	MDL NO. 1203
)	
THIS DOCUMENT RELATES TO:)	
)	
SHEILA BROWN, et al.)	
)	CIVIL ACTION NO. 99-20593
v.)	
)	
AMERICAN HOME PRODUCTS CORPORATION)	2:16 MD 1203
)	

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8595

Bartle, C.J.

February 3, 2011

The Estate of Leslie D. Woolfolk ("Estate"), a representative claimant under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether the Estate has demonstrated a reasonable medical basis to support its claim for Matrix Compensation Benefits ("Matrix Benefits").²

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify Diet Drug Recipients for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to the Diet Drug Recipient's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. &

(continued...)

To seek Matrix Benefits, a representative claimant³ must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The representative claimant completes Part I of the Green Form. Part II is completed by an attesting physician, who must answer a series of questions concerning the deceased's medical conditions that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, if the representative claimant is represented by an attorney, the attorney must complete Part III.

In September, 2003, Cheryl Irvine, the representative of Leslie D. Woolfolk's ("Ms. Woolfolk") estate, submitted a supplemental completed Green Form to the Trust signed by the attesting physician, Duane Bridges, M.D. Based on an echocardiogram dated March 6, 2002, Dr. Bridges attested in Part II of the Green Form that Ms. Woolfolk suffered from moderate mitral regurgitation, an abnormal left atrial dimension, a

2. (...continued)

IV.B.2.d(1)-(2). Matrix A-1 describes the compensation available to representative claimants where the Diet Drug Recipients are diagnosed with serious VHD, they took the drugs for 61 days or longer, and they did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to representative claimants where the Diet Drug Recipients were registered as having only mild mitral regurgitation by the close of the Screening Period, they took the drugs for 60 days or less, or they were diagnosed with conditions that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

3. Under the Settlement Agreement, representative claimants include estates, administrators or other legal representatives, heirs or beneficiaries. See Settlement Agreement § II.B.

reduced ejection fraction in the range of 50% to 60%, severe regurgitation and the presence of ACC/AHA Class I indications for surgery to repair or replace the mitral valve where such surgery was not performed, and New York Heart Association Functional Class III symptoms. He also attested that Ms. Woolfolk's death resulted from a condition caused by valvular heart disease or valvular repair/replacement surgery. Based on such findings, the Estate would be entitled to Matrix A-1, Level V⁴ benefits in the amount of \$853,599.⁵

In April, 2004, the Trust forwarded the claim for review by Ioannis P. Panidis, M.D., F.A.C.C., one of its auditing cardiologists. In audit, Dr. Panidis concluded that there was no reasonable medical basis for the finding of Dr. Bridges that Ms. Woolfolk's death resulted from a condition caused by valvular heart disease or valvular repair/replacement surgery stating, in relevant part, that:

4. Under the Settlement Agreement, a claimant or representative claimant is entitled to Level V Matrix Benefits if the Diet Drug Recipient suffered "[d]eath resulting from a condition caused by valvular heart disease or valvular repair/replacement surgery which occurred post-Pondimin® and/or Redux™ use supported by a statement from the attending Board-Certified Cardiothoracic Surgeon or Board-Certified Cardiologist, supported by medical records[.]" See Settlement Agreement § IV.B.2.c.(5)(c).

5. In April, 2002, Ms. Woolfolk was paid Matrix A-1, Level II benefits in the amount of \$643,500. According to the Trust, if the Estate is entitled to Matrix A-1, Level V benefits, the Estate would be entitled to benefits in the amount of \$1,467,099. The amount at issue, therefore, is the difference between the Level II Matrix Benefits already paid and the amount of Level V Matrix Benefits.

Patient's primary medical conditions were dilated cardiomyopathy, congestive heart failure and hyperthyroidism, mitral regurgitation was secondary to her left ventricular dysfunction and not a primary problem. Death was likely due to a sudden ventricular arrhythmia (ventricular tachycardia/fibrillation).⁶

Based on the auditing cardiologist's findings, the Trust issued a post-audit determination denying the claim. Pursuant to the Rules for Audit of Matrix Compensation Claims ("Audit Rules"), the Estate contested this adverse determination.⁷ In contest, the Estate did not present any additional materials in support of the contention that it was entitled to Level V benefits because Ms. Woolfolk's death resulted from a condition caused by valvular heart disease or

6. Dr. Panidis also determined that there was no reasonable medical basis for the attesting physician's finding that Ms. Woolfolk had an abnormal left atrial dimension and severe regurgitation and ACC/AHA Class I indications for surgery. In addition, Dr. Panidis found that there was no reasonable basis for the attesting physician's failure to find that Ms. Woolfolk suffered from pulmonary hypertension secondary to moderate mitral regurgitation, a left ventricular end-systolic dimension greater than or equal to 45 mm. Dr. Panidis further concluded that Ms. Woolfolk's ejection fraction was less than 30%, not in the range of 50% to 60% as attested to by Dr. Bridges. Finally, Dr. Panidis confirmed that Ms. Woolfolk had moderate mitral regurgitation. These conditions, however, are not at issue in this claim.

7. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to the Estate's claim.

valvular repair/replacement surgery. Instead, the Estate argued that it was entitled to Level V benefits because the Trust previously accepted Ms. Woolfolk's claim for Level II benefits⁸ and the finding of Dr. Panidis that Ms. Woolfolk's "[d]eath was likely due to a sudden ventricular arrhythmia (ventricular tachycardia/fibrillation)." Under the Settlement Agreement, a claimant or representative claimant is entitled to Level V Matrix Benefits if the Diet Drug Recipient qualifies for Level II benefits and suffers from ventricular fibrillation or sustained ventricular tachycardia which results in hemodynamic compromise. See Settlement Agreement § IV.B.2.c.(5)(d).

After receipt of the Estate's contest materials, the Trust forwarded the claim for a second review by the auditing cardiologist. Dr. Panidis determined that the medical records were incomplete. Accordingly, the Trust requested that the Estate submit additional medical records that were required "in order to process the Claimant's Contest and issue a Final Post-Audit Determination Letter."

In response, the Estate provided the requested records. With this submission, the Estate also provided a second supplemental Green Form signed by the attesting physician,

8. The Estate also noted that Dr. Panidis determined that the echocardiogram of March 6, 2002 also entitled Ms. Woolfolk to Level II benefits because it demonstrated moderate mitral regurgitation, a reduced ejection fraction of less than 30%, pulmonary hypertension secondary to moderate or greater mitral regurgitation, and an abnormal left ventricular end-systolic dimension.

Stephen Raskin, M.D., who, according to the Estate, "totally agrees with Dr. Panidis." Based on the March 6, 2002 echocardiogram, Dr. Raskin attested that Ms. Woolfolk had moderate mitral regurgitation, an abnormal left ventricular end-systolic dimension, a reduced ejection fraction of less than 30%, New York Heart Association Functional Class III symptoms, and ventricular fibrillation or sustained ventricular tachycardia which results in hemodynamic compromise.⁹

The Trust then submitted the claim, including the additional medical records and second supplemental Green Form, for a third review by the auditing cardiologist. Thereafter, Dr. Panidis provided a declaration wherein he confirmed his finding at audit that Ms. Woolfolk's "death did not result from valvular heart disease or valvular repair/replacement surgery." Dr. Panidis also addressed his "hypothesi[s] that 'death was likely due to a sudden ventricular arrhythmia (ventricular tachycardia/ fibrillation).'" Specifically, Dr. Panidis stated:

I have reviewed the new medical records submitted by the Estate, as well as Ms. Woolfolk's death certificate and echocardiograms. Ms. Woolfolk's medical records do not mention that she suffered from ventricular fibrillation or sustained ventricular tachycardia which results in hemodynamic compromise. Her hyperthyroidism and cardiomyopathy are well documented in the medical records. Her death could have been caused by any one or combination of factors, including a cardiomyopathy, pulmonary embolism, pulmonary edema, thyroid storm,

9. The Estate stated that it "hereby withdraws Dr. Bridges' physician declaration and replaces it with Dr. Raskin's."

ventricular arrhythmia (ventricular tachycardia/fibrillation) and bradycardic asystolic cardiac arrest.

The Trust then issued a final post-audit determination, again denying the claim. In support, the Trust noted that the Estate did not submit any materials in support of its claim that Ms. Woolfolk suffered death as a result of a condition caused by valvular heart disease. The Trust also asserted that the submission of a second supplemental Green Form "effectively constitutes a 'withdrawal' of the original Green Form claim. Under Audit Rule 40, this withdrawal closes Claimant's claim 'as to any condition that has been claimed or *could have been claimed* as of the date of the Attesting Physician's signature on Part II of the Green Form.'" (Emphasis in original) (citation omitted). According to the Trust, the second supplemental Green Form is barred as it "is not based on a *subsequent* echocardiogram" and "does not allege a change in Claimant's medical condition." (Emphasis in original.)

The Estate disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why the claim should be paid. On October 26, 2005, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 5811 (Oct. 26, 2005).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. The Estate then served a response upon the Special Master. The Trust submitted a reply on April 12, 2007. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor¹⁰ to review claims after the Trust and the Estate have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and the Estate and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether the Estate has met its burden in proving that there is a reasonable medical basis for its claim for Matrix A-1, Level V benefits. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the claim, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the

10. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. U.S., 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

other hand, we determine that there is a reasonable medical basis for the claim, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b) .

In support of its claim, the Estate argues that it has established a reasonable medical basis for the claim for Level V benefits because the Trust's auditing cardiologist concluded that Ms. Woolfolk's death was a result of, at least in part, ventricular fibrillation or tachycardia, which is an independent basis for Level V benefits under the Settlement Agreement. The Estate also argues that it should not be deemed to have withdrawn the claim for Level V benefits by submitting a second supplemental Green Form asserting a different basis for Level V benefits. In support, the Estate asserts that the additional medical condition was based on a determination of the Trust's auditing cardiologist and that the Trust had the auditing cardiologist address the additional basis in a supplemental declaration.

In response, the Trust argues that the Estate did not rebut the auditing cardiologist's determination that Ms. Woolfolk's death did not result from a condition caused by valvular heart disease and that the Estate, in submitting a second supplemental Green Form, should be deemed to have withdrawn its original Level V claim. The Trust also asserts that the Estate should not prevail because there has not been an audit of the Estate's alternative basis for Level V benefits.

The Technical Advisor, Dr. Vigilante, reviewed the Show Cause Record, including Ms. Woolfolk's medical records and three echocardiogram tapes, and concluded that there was no reasonable basis for the representation of Dr. Bridges that Ms. Woolfolk's death resulted from valvular heart disease. Dr. Vigilante, however, concluded that there was a reasonable medical basis for Dr. Raskin's representation that Ms. Woolfolk had ventricular fibrillation or sustained ventricular tachycardia which results in hemodynamic compromise. In particular, Dr. Vigilante determined that:

According to the Certificate of Death, Ms. Woolfolk had sudden cardiac death on August 24, 2003. There was no documentation that Ms. Woolfolk had any symptoms immediately prior to her death. Therefore, the most likely cause of her death was a sudden arrhythmic event related to her cardiomyopathy. Most commonly, this arrhythmia is ventricular tachycardia degenerating into ventricular fibrillation resulting in death. It is unlikely that Ms. Woolfolk's death was related to pulmonary embolism, pulmonary edema without symptomatic shortness of breath, or thyroid storm alone. A bradycardic asystolic cardiac arrest is less common than a ventricular arrhythmia in the sudden death of a patient with a dilated cardiomyopathy. Indeed, this is the reason why internal cardioverter/defibrillators are indicated in patients with dilated cardiomyopathy and low ejection fraction to decrease the incidence of sudden cardiac death. Although there were no medical records or any autopsy reflecting the exact cause of Ms. Woolfolk's death, the most likely cause of death was a sudden ventricular arrhythmia as described above. It is likely that Ms. Woolfolk's arrhythmia and subsequent sudden death were exacerbated by her severe thyroid abnormalities.

In response to the Technical Advisor Report, the Trust submitted a letter in which it objected to the Technical Advisor Report on three grounds. First, the Trust argues that the Technical Advisor should not have been asked to opine as to whether Ms. Woolfolk suffered from ventricular fibrillation or sustained ventricular tachycardia which results in hemodynamic compromise because "[i]t can only be assumed that the foregoing question was derived from a Green Form Part II proffered in Contest by a physician other than the attesting physician in this matter." According to the Trust, the Green Form signed by Dr. Raskin and submitted by the Estate in response to the Trust's post-audit determination constitutes an impermissible new claim pursuant to Audit Rule 46. Second, the Trust asserts that although the auditing cardiologist and Technical Advisor "speculated" that Ms. Woolfolk suffered death as a result of a ventricular arrhythmia, neither opined that there was no reasonable medical basis for the representation by Dr. Bridges that Ms. Woolfolk did not suffer from ventricular fibrillation or sustained ventricular tachycardia which results in hemodynamic compromise. Finally, the Trust contends that the Estate's claim based on ventricular fibrillation or sustained ventricular tachycardia which results in hemodynamic compromise cannot be paid because such payment would violate PTO No. 2662, which requires the audit of all matrix claims. According to the Trust, "[t]o the extent that Claimant wishes to pursue a Supplemental Claim pursuant to Section IV.B.2.c.(5)(d), the Estate should be

required to file and complete said claim for processing by the Trust including audit by an independent auditing cardiologist"

The Estate also responded to the Technical Advisor Report. The Estate argues that Dr. Vigilante determined that "[t]here is a reasonable medical for the Attesting Physician's answer to Green Form Question L.5.... [T]he most likely cause of death was a ventricular arrhythmia...." In addition, the Estate contends that the Trust's position that the claim should be precluded "is contrary to the Settlement Agreement, inequitable and contrary to a claimant's normal right to assert alternate and/or multiple theories in support of the same claim." The Estate also argues that Audit Rule 40 is inconsistent with Section VI.C.3.(b) of the Settlement Agreement, which "afford[s] each Class Member at least three (3) separate opportunities to supply any missing or omitted information and document which are necessary to support a Claim for Benefits under the Settlement Agreement." According to the Estate, it supplied the documents necessary to support its claim because it "promptly submitted a new Green Form that matched the Level V qualifying arrhythmia findings of the Trust's own auditing physician and the express terms of the the Class Settlement permit and encourage such supplementation."

After reviewing the entire Show Cause Record, we find that the Estate has established a reasonable medical basis for its Level V claim for Matrix Benefits. Under the Settlement

Agreement, a claimant or representative claimant is entitled to Level V Matrix Benefits if the following definition is met:

- (d) The individual otherwise qualifies for payment at Matrix Level II, III, or IV and suffers from ventricular fibrillation or sustained ventricular tachycardia which results in hemodynamic compromise.

Settlement Agreement § IV.B.2.c.(5)(d).

In the present case, the Trust does not contest that Ms. Woolfolk qualified for Level II Matrix Benefits. Thus, the initial prerequisite for this Level V claim is not in dispute. As to the remaining requirement for this claim, the Trust's auditing cardiologist concluded that Ms. Woolfolk's "[d]eath was likely due to a sudden ventricular arrhythmia (ventricular tachycardia/fibrillation)." Consistent with this finding, the Estate submitted a supplemental Green Form, attested to by another attesting physician,¹¹ that Ms. Woolfolk suffered from ventricular fibrillation or sustained ventricular tachycardia which results in hemodynamic compromise. Although the Trust's auditing cardiologist asserted in a subsequent declaration that he merely had "hypothesized" that Ms. Woolfolk's death was likely due to this condition, the auditing cardiologist conceded that Ms. Woolfolk's death "could have been caused by any one of a

11. As explained by the Estate, a different attestation was obtained because the initial attesting physician was requested to determine an alternative basis for a Level V claim, namely, that Ms. Woolfolk's death resulted from valvular heart disease. The Show Cause Record contains a letter from the Estate's counsel, which reflects this request.

combination of factors," including "ventricular arrhythmia (ventricular tachycardia/fibrillation)."

In addition, the Technical Advisor, Dr. Vigilante, reviewed Ms. Woolfolk's medical records and agreed with the auditing cardiologist's initial conclusion that Ms. Woolfolk died as a result of ventricular arrhythmia (ventricular tachycardia/fibrillation). Specifically, Dr. Vigilante determined that there was a reasonable medical basis for the representation that Ms. Woolfolk suffered from ventricular fibrillation or sustained ventricular tachycardia which results in hemodynamic compromise. Dr. Vigilante explained that "the most likely cause of her death was a sudden arrhythmic event related to her cardiomyopathy. Most commonly, this arrhythmia is ventricular tachycardia degenerating into ventricular fibrillation resulting in death." Dr. Vigilante also excluded the other potential causes of Ms. Woolfolk's death identified by Dr. Panidis, including pulmonary embolism, pulmonary edema, thyroid storm, and bradycardic asystolic cardiac arrest. Although the Trust responded to the Technical Advisor Report, it does not contest that Ms. Woolfolk suffered from ventricular fibrillation or sustained ventricular tachycardia which results in hemodynamic compromise. The Estate, therefore, has satisfied its burden in these Show Cause proceedings.

In general, the court will not permit a claimant or representative claimant to abandon a claim found not payable by the Trust after audit and rely on entirely new grounds to receive

Matrix Benefits. Here, however, the Trust's auditing cardiologist suggested that Ms. Woolfolk had a required medical condition for Matrix Benefits. The Estate then submitted an additional attestation form reflecting the condition at issue and explained why the medical condition was not identified in its original Green Form. Finally, the Technical Advisor determined that there was a reasonable medical basis for the representation that Ms. Woolfolk suffered from ventricular fibrillation or sustained ventricular tachycardia which results in hemodynamic compromise. Accordingly, under these particular circumstances, we conclude that the Estate has established its entitlement to Level V Matrix Benefits.

We also reject the Trust's assertion that the present claim should not be paid because it has not been audited. As reflected in both the auditing cardiologist's initial certification and subsequent declaration, the issue of ventricular fibrillation and sustained ventricular tachycardia which results in hemodynamic compromise was addressed by the auditing cardiologist.

For the foregoing reasons, we conclude that the Estate has met its burden of proving that there is a reasonable medical basis for its claim and is consequently entitled to Matrix A-1, Level V benefits. Therefore, we will reverse the Trust's denial of the Estate's claim for Matrix Benefits.